AUG 2 2 2003

EXHIBIT #1
4 pages

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

1. **Submitter's Identification:**

Viatronix Inc.
25 East Loop Road
Suite 203/ 204
Stony Brook, NY 11790
Establishment Registration number- 2438935

Contact: Baman Pattanayak, Regulatory Consultant

Date Summary Prepared:

July 19, 2003

2. **Name of the Device:**

a) Device trade name: Viatronix V3D Explorer, revision 1.2
b) Device common name: Medical Image processing software system
c) Classification name: 90LLZ- Image Processing system

3. **Predicate Device Information:**

Predicate Device #1: G.E. Navigator, 510(k) # K954355. This system is an add-on to the Advantage Windows Workstation. Many features in the manual reference the base workstation manuals.

Predicate Device #2: Vital Images Vitrea 2, Version 2.1, 510(k) # K002519.

Predicate Device #3: Viatronix Visualization System, 510(k) # K002780. This system name is sometimes abbreviated as VVS.

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4. **Device Description:**

The V-3D Explorer is a software device for evaluating CT/MRI scanned and X-Ray images of selected human organ. It is an additional image processing option added to our V-3D visualization system for which pre-market clearance was granted by the FDA vide K#002780, dated November 17, 2000. It is a general software module, designed for use as a part of our V-3D visualization system core technology. The system consists of a V-3D processor and a V-3D viewer in two computer configuration or V-3D processor and V3D viewer in a stand alone one computer configuration. Upon receipt of a multi-slice CT / MR scan image or X-Ray image for any selected organ in a DICOM format, the V-3D processor converts the DICOM image data into an internally recognized volume data format using our core software technology. The V-3D viewer provides interactive orthogonal and multiplanar reformatted 2D and 3D images from the V-3D processor and user can evaluate these images for any abnormality or malformation in specified organs obtained from scanned images or X-Ray images. The volume, linear and angular measurement features provided in the software for the evaluation and quantification of organ volume, linear measurements, angular location/displacement for hard and soft tissues as well as internal organ structures for polyp, lesion, mass, tumor, implants, fracture, aneurysms, stenoses etc. The software also supports interactive segmentation of any organ from removing certain structure from display for critical evaluation of selected part of organ. The intended user can use the software device to acquire, process, render, evaluate, archive, print and distribute DICOM 3.0 compliant images of any organ, utilizing PC hardware.

5. **Indications for Use:**

The Viatronix V3D Explorer is intended to be used for the display and 2D/3D visualization of medical image data derived from CT, MRI, PET, SPECT scans and X-Ray of the human body including any organ. The volume, linear and angular measurement functions are intended for the evaluation and quantification of tumor or selected organ volume/linear measurements, angular location/ displacement, study/ analysis and evaluation of both hard and soft tissues as well as other internal organ structures for polyp, lesion, mass, implants, fracture, aneurysms, stenoses etc or evaluation of any abnormality / malformation in specified organs obtained from scanning and X-Ray. It also supports the interactive segmentation of any organ by removing certain structure(s) from display for critical evaluation of selected part(s) of organ. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, evaluate, archive, print and distribute DICOM 3.0 compliant specified organ image studies, utilizing PC hardware.

6. **Comparison to Predicate Devices:**

The Viatronix V3D Explorer Module (V3D Explorer) utilizes the same technological characteristics as the three predicate devices. All provide multi-view user

interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. All provide window/level adjustment of the 2D and 3D views to enhance features, provide measurement tools for analysis of the observed structures, provide region of interest selection tools to isolate specific features, provide annotation tools to help indicate and describe findings, and provide integrated reporting to distribute the findings.

V3D Explorer and all three predicates provide external 3D views. As with Vitrea 2 and VVS, the V3D Explorer Module utilizes direct volume rendering for all of its 3D views, including transparent volume images and visible surface views. G.E. Navigator utilizes surface extraction techniques for all 3D views. For changing the mapping to opacity during translucent views, V3D Explorer is similar to Vitrea 2 and VVS devices because all use the same technique of volume rendering.

We conclude that the subject device, the Viatronix V3D Explorer, is as safe and effective as the predicate devices and poses no new questions of safety and effectiveness.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Scanned image or X-Ray datasets of various patients organs with known abnormalities or status were used as input for testing of software functionalities in accordance with a test protocol. The V3D Explorer software module provided interactive orthogonal and multiplanar reformatted 2D and 3D images from datasets to detect and evaluate the known abnormalities or status of organs. The volume, linear and angular measurement features provided in the software were used to evaluate and quantify any abnormality of organs or status of any internal organ structures.
The V3D Explorer Module has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. Testing on phantom datasets has determined its level of accuracy, which correlates perfectly with pre-calculated values. The product has shown itself to be reliable, easy to use and capable of evaluating DICOM 3.0 compliant scanned images or X-Ray images of any human organs.
We conclude from these tests that V3D Explorer module is substantially equivalent to the predicate devices in its ability to evaluate any human organs.

8. **Discussion of Clinical Tests\Evaluations Performed:**

Tests and validations on Patients' various organs were performed per protocol. Loaded Patients' scanned organs images to the predicate device. Evaluated various organs using the predicate device and recorded the results of evaluation and quantification.

Same scanned organ images were loaded into the Viatronix V3D Explorer application. Evaluated all Patients' various organs using V3D Explorer application, and

recorded the results of evaluation and quantification. DICOM compliant X-Ray images data were loaded intoV3D Explorer application and ensured that the X-Ray data source is processed and converted correctly. Evaluated various organs. Evaluation results indicated that 2D projection cases as well as 3D reconstructed cases were correctly processed and converted, allowing for an accurate display and evaluation. In addition phantom data showed that the measurements are accurate and the V3D Explorer is evaluated to be safe and effective.

Evaluation results of both predicate device and V3D Explorer device were same and no significant differences were detected in the results of evaluation.

In conclusion, it was established that the V3D Explorer application is substantially equivalent to the predicate devices.

9. **Conclusions:**

The Viatronix V3D Explorer has the same intended use and similar technological characteristics as the GE Navigator (K # 954355) Vital Images Vitrea 2, Version 2.1 (K # 002519) and Viatronix Visualization System (K# 002780). Moreover, tests and validations using Patients' Image data and non-clinical tests performed demonstrated that the Viatronix V3D Explorer application is substantially equivalent to the predicate devices in its ability to review, analyze and evaluate CT/ MR scan images or X-Ray images of various organs to facilitate analysis and evaluation of abnormality or malformation in organs by a trained physician. The Viatronix V3D Explorer application does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

Viatronix, Inc.
% Mr. Jeff D. Rongero
Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K032483
Trade/Device Name: Viatronix V3D Explorer
Revision 1.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 11, 2003
Received: August 12, 2003

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

INDICATIONS FOR USE

510(k) Number (if known): K032483

Device Name: Viatronix V3D Explorer, revision 1.2

Indications For Use:

The Viatronix V3D Explorer is intended to be used for the display and 2D/3D visualization of medical image data derived from CT, MRI, PET, SPECT scans and X-Ray of the human body including any organ. The volume, linear and angular measurement functions are intended for the evaluation and quantification of tumor or selected organ volume/linear measurements, angular location/ displacement, study/ analysis and evaluation of both hard and soft tissues as well as other internal organ structures for polyp, lesion, mass, implants, fracture, aneurysms, stenoses etc or evaluation of any abnormality / malformation in specified organs obtained from scanning and/or X-Ray. It also supports the interactive segmentation of any organ by removing certain structure(s) from display for critical evaluation of selected part(s) of organ. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, evaluate, archive, print and distribute DICOM compliant specified organ image studies, utilizing PC hardware.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

David A. Lilyquist

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032483